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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,347	01/19/2001	Raghavan Rajagopalan	MRD-60	7678

7590

02/03/2003

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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,347

Applicant(s)

RAJAGOPALAN ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

Art Unit: 1641

1) Claim 11 appears to be missing words. There is no antecedent basis in step (b) for "said target tissues" and there is no indication in the claim of the recipient of the "phototherapeutic procedure".

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to azide-substituted receptor-compound conjugates, classified based on the structure of the "organic azide compound", for example, in classes 530 and 536.
- II. Claim 11 (part), drawn to a method of performing a therapeutic procedure using an organic azide compound ($E = H$), classified in class 514 based on the structure of the final product, for example, in different subclasses for each of "pyrroles", "quinolines", and "xanthenes".
- III. Claims 11 (part) and 12-27, drawn to a method of performing a therapeutic procedure using azide conjugates of receptor binding molecules, classified in class 514; subclasses based on the structure of the "organic azide photosensitizer" including the "receptor binding molecule".

3) The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the dye-"receptor binding molecule" conjugate of Invention I could be used as a reagent in an immunoassay to determine the presence of the corresponding "receptor" moiety in a biological sample.

b) Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

Art Unit: 1641

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the phototherapy method of II does not use any of the "organic azide compounds" defined in claim 1, i.e., "E" is not defined as H in claim 1. Similarly, the methods of Inventions II and III are unrelated since the methods use chemically different "organic azide photosensitizers" (i.e. the definitions of "E" are different).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring different fields of search and different patentability considerations, restriction for examination purposes as indicated is proper.

4) Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5) Each "organic azide photosensitizer" as defined in claims 1 and 11 constitutes a separate and distinct invention since the various dye types ("Ar") and "receptor binding molecules" ("E") are structurally and functionally different in nature. In addition to electing any one of Inventions I-III above, applicants must further **elect a specific species** of "organic azide photosensitizer" as set forth in claim 1, i.e. applicants must elect a specific chemical definition for each of "E" and "Ar" to define the elected "organic azide photosensitizer" invention and must indicate **a)** at what positions on the structure "Ar" the groups "L" and "X" are attached and **b)** at what position on the structure "E" the group "L" is attached.

6) Applicants are advised that the claims will be subject to rejection under 35 USC 112, first and second paragraphs, with regard to **a)** the definitions of "Ar" and **b)** the definition of "E" as hydrogen (claim 11).

a) The only definitions of the term "Ar" appear at page 7, line 2 *et seq* and page 11, line 8 *et seq* of the specification. The terms "benzenes", "purines", "carbazoles", etc. do not

Art Unit: 1641

adequately specify the nature and number of the other substituents and/or multiple rings which are implied by the plural designations. Although the claims and specification define the nature and function of the variables "E", "L", and "X", the nature and functional requirements of "Ar" are unspecified.

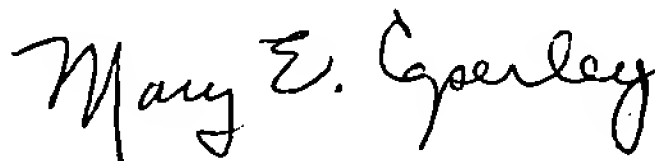
b) It would appear that the phototherapeutic method of claim 11, wherein $E = H$ would not be operative, since there would be no moiety on the photosensitizer which would bind to a site requiring phototherapy.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

February 1, 2003


Mary E. (Molly) Ceperley
Primary Examiner
Art Unit 1641